DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

April 8, 2015

Mennen Medical Ltd.
c/o Mr. Ifat Shwarts
QA & RA Manager
4 Ha-yarden St. Yavne 8122804
P.O. Box 102 Rehovot 7610002
Yavne, 8122804 IL

Re: K141441
Trade/Device Name: Menntor X7
Regulation Number: 21 CFR 870.1025
Regulation Name: Arrhythmia Detector and Alarm (Including ST-Segment Measurement and Alarm)
Regulatory Class: Class II
Product Code: DSI
Dated: November 6, 2014
Received: November 10, 2014

Dear Mr. Ifat Shwarts,

This letter corrects our substantially equivalent letter of January 9, 2015.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

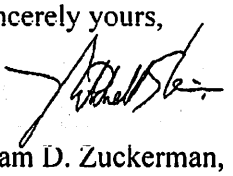
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

Device Name: **Menntor X7.**

Menntor X7 is intended for use as a multi-parameter physiological patient monitoring system.

The Menntor X7, is a modular monitor with a Multi Parameter Module (MX57, MPM) that can monitor ECG/heart rate, invasive blood pressures , temperature, pulse oximetry, respiration, non-invasive blood pressure, and Cardiac Output

The Menntor X7 can also monitor EtCO2, Spirometry and EEG, and display aEEG.

The MPM (MX57) is equipped with a battery and can continue monitoring it's vital sign when out of the host Menntor X7

This effectively allows the Menntor X7 to monitor a wide-range of adult, pediatric and neonatal patient conditions, in many different areas of the hospital.

Functions include display of multi-parameter waveforms, vital signs, alarm & status messages.

The Mennen Medical Menntor X7 is intended for sale as a system for monitoring and recording patient information on any in-hospital application requiring patient monitoring.

The following are examples of intended clinical applications:

- Critical Care Patients
- Cardiac Step-down Units
- Emergency Departments
- Intra-operative (Anesthesia) Monitoring
- Post Anesthesia Care

*The Intended Use of the Menntor X7 as indicated above is same as the Indications For Use.

Prescription Use YES (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use NO (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Traditional 510(k): Device Modification – Menntor X7

Date: May 25, 2014

Topic: **510K for *Menntor X7 monitor***

Establishment Name, Registration Number and Address:

Name:	Mennen Medical Ltd.
Registration Number:	9611022
Operator Number:	9069173
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Contact person:	Ifat Shwarts, Regulatory Affairs

To: Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville MD, 20850

Attn.: Document Control Clerk
From: Ifat Shwarts, Regulatory Affairs

Attached please find a hard copy of our 510K submission.
Additional electronic copy (which is an exact duplicate of the paper copy) of the submission is attached on CD

The following information is being submitted in conformance with 21 CFR 807.87:

1.	Classification Name	Detector and Alarm, Arrhythmia
2.	Classification Number:	21 CFR 870.1025
3.	Common/Usual Name	Physiological Patient Monitor
4.	Trade/Proprietary Name	Menntor X7
5.	Part Number	791-000-000
6.	Establishment Registration Number	9611022
7.	FDA Classification	Class II
8.	Product Code	DSI
9.	Reviewing Panel	Cardiovascular
10.	Performance Standards	Please see page 15, 16
11.	510(k) Marketing clearance for VitaLogik 6000	K093766 – May 7, 2010

Terminology

Menntor X7 = subject of this Traditional 510(k). The Menntor X7 is a modified device, of the VitaLogik 6000/6500 Patient Monitor and of the Envoy monitor Spirometry module

VitaLogik 6000/6500 Patient Monitor = the predicate device.
The VitaLogik 6000/6500 was approved for marketing by the FDA in (K093766 dated 5.7.2010) and also with CerebraLogik in (**K131789 dated 27.12.2013**)
Envoy monitor with Spirometry module = the predicated device
The Envoy monitor was approved for marketing by FDA (K030722 dated 26.2.2004)

Definition of Product Family:

The Menntor X7 is a new member of the Envoy /VitaLogik family.

It uses the same GUI and data storage capabilities, as the other monitors

It can be viewed by the Ensemble central nurse station and by the Enguard remote monitor, as all other members of the family..

Data transfer and remote view is available between all members of the family.

The new Menntor X7 will measure, display and store the same vital signs as does the VitaLogik 6000/6500, plus Spirometry, same as on the Envoy monitor.

1. Device Description: Menntor X7

The Menntor X7 is a modular multi-parameter physiological patient monitor, based on the hardware and software of the Mennen Medical VitaLogik 6000/6500 and Envoy monitors, with integrated display screen. It is part of the Envoy/VitaLogik Monitor family and runs on same software versions.
In general, the Menntor X7 has the same functions, similar intended use and technology as the other members of the Mennen Medical monitor family.

The Menntor X7 uses identical display format and patient data as does the VitaLogik 6000/6500 monitor. The Ensemble central station and the Enguard remote monitor can both view the Menntor X7 as well as the other members of the family: VitaLogik 6000/6500, VitaLogik 4000/4500, VitaLogik 5000/ 5500 and Envoy.

The Menntor X7 bedside patient monitor consists of MX57 - Multi Parameter plug in Module, (MPM), two additional single parameters plug in modules, a main processing unit, and an integrated color monitor with optional touch screen.
The front end electronics incorporated in the MPM has same hardware and software as VitaLogik 6000/6500 . The input connectors are incorporated in the side panel of the MPM.
The MPM (MX57) has an optional 5.7" display, that enables the MPM to continue monitoring when taken out of the Menntor X7 host.
The Menntor X7 monitor presents vital signs in the same way and the same GUI (Graphic User Interface) as does the VitaLogik 6000/6500 monitor.
The Menntor X7 can acquire the following physiological signals of the patient:
• ECG – Waveform, Arrhythmia and numeric values of Heart Rate, and ST

- Blood Pressures – Waveform and numeric values of, Diastole and Mean pressure
- Temperature – As a numeric value in C° or F°
- SpO2 – Photoplethysmographic waveform and numeric value of the oxygen saturation and pulse rate
- NIBP – Systolic, Diastolic and Mean pressure with measuring time stamp
- EtCO2 – EtCO2, inCO2 and Respiration Rate
- Spirometry
- EEG and aEEG.

Functional Description of the Menntor X7

The Menntor X7 is a modular monitor, based on the Envoy monitor for Spirometry and on VitaLogik 6000/6500 monitor for all other vital signs.
It differs in hardware but uses the same software versions for display and data storage.
It uses the Multi Parameter Module (MPM) to measures vital signs such as ECG/Heart rate, NIBP, SpO2, Temperature, Invasive pressures, Cardiac output.
It uses plug in modules to measure EtCO2 and Spirometry.

The Menntor X7 uses identical display format and patient data as do the VitaLogik 6000/6500 monitor. The Ensemble central station and the Enguard remote monitor can both view the Menntor X7, VitaLogik 6000/6500, VitaLogik 4000/4500, VitaLogik 5000/ 5500 as well as the Envoy.
The Menntor X7 has two serial inputs for interface with other vendor devices in the same way as the serial input on VitaLogik 6000/6500.

Menntor X7: Vital signs parameters

- Diagnostic 7 or 12 Lead ECG
- Non-invasive Blood Pressure
- Pulse Oximetry (SpO2)
- Temperature
- 2 (optional 4) Invasive Blood Pressure channels
- Cardiac Output
- EtCO2 (Module)
- Spirometry (Module)
- CerebraLogik – EEG & aEEG

Main components of the Menntor X7:

The Menntor X7 system consists of:

(A) Menntor X7 host monitor with integrated Display
Acquires, processes, and converts vital signs from the patient into waveforms and digital signals, and stores vital signs waveforms and the numeric parameters

(B) The Multi-Parameter Module. (MPM)

The Menntor X7 uses a plug in MPM to acquire the following physiological

signals of the patient:

- ECG – Waveform , Arrhythmia and numeric values of Heart Rate, and ST
- Blood Pressures – Waveform and numeric values Systole, Diastole and Mean pressure
- SpO2 – Photoplethysmographic waveform and numeric value of the oxygen saturation and pulse rate
- NIBP – Systolic, Diastolic and Mean pressure with measuring time
- Temperature – As a numeric value in C° or F°

It uses also two plug-in modules to measure:

- EtCO2 – EtCO2, inCO2 and Respiration Rate
- Spirometry – Flow, Volume and Airway pressure waveforms, and numeric parameters of the pulmonary mechanics

Reasons for developing the Menntor X7 :
The Menntor X7 was developed for those users that wish to have a modular patient monitor with in-built display. It uses the capabilities of the other members of Mennen Medical monitor family, and same menus and display options.

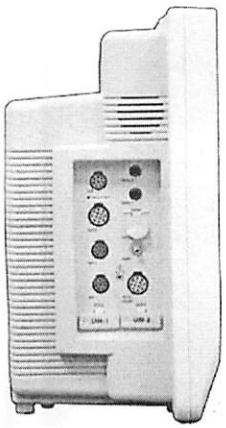
The main advantages of the Menntor X7 are:

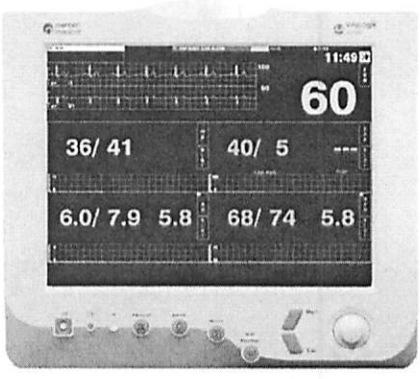
1. Multi Parameter plug-in Module (MPM)
2. Optional Wireless LAN
3 Battery operated MPM
4. Same user interface as **VitaLogik** and Envoy **monitors**
5. Full compatibility with Ensemble Central station
6. Full compatibility with Enguard remote monitor

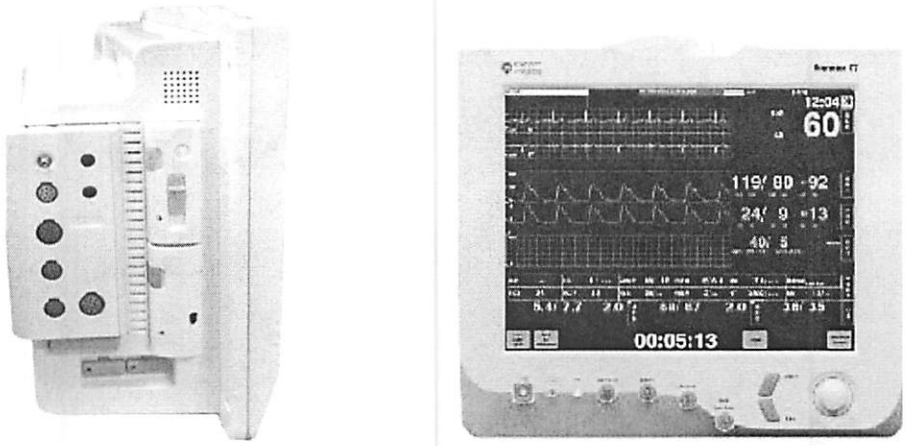
Substantiel Equivalence of Menntor X7 to VitaLogik 6000/6500 and to Envoy Spirometry module

Comparison: **Menntor X7** with **VitaLogik 6000/6500**

VitaLogik 6000/6500 – side view and front view







Menntor X7 – Side View and front view

The major differences between the Menntor X7 and the VitaLogik 6000/6500 are:

1. The Menntor X7 is a modular monitor while it's predicated device the VitaLogik 6000/6500 is a configured monitor
2. Menntor X7 has a Spirometry module based on the Envoy monitor as it's predicated device

12. Device comparison: Menntor X7 versus VitaLogik 6000/6500

Comparison: Menntor X7 with VitaLogik 6000/6500

The following table summarize and compare data of the VitaLogik 6000/6500, Predicated device, to the subject of this submission, the Menntor X7.

	VitaLogik 6000/6500	**Menntor X7**
Part/Option Number	781-100-000	791-000-000
510 K	K093766 – 05/07/2010 K131789 – 12/27/2013	
Input Circuit Parameters	Configured	2 Plug–in modules Plug-in Multi Parameter Module (MPM)
Chassis Leakage Current	All patient signal inputs fully isolated (<50 μA) Meets or exceeds ANSI standard: "Safe Current Limits for Electromedical Aparatus," (SCLE) Dec, 1978 item 2.1.1.	Same
Hardware comparison		

	VitaLogik 6000/6500	Menntor X7
Front End electronics	Integrated front end electronics	Plug-in MPM
Front Panel keys	5	Same
Quicknobe	Yes	Same
Main screen	Yes	Same
Escape	Yes	Same
Silence – Red	Yes	Same
Alarm Off – Red	No	Yes
Print – Green	Yes	same
NIBP Start/Stop – Yellow	Yes	Same
Main Menu		
Vital Signs	Fixed list of vital signs	Same
Patient data	List of patient data	Same
Setup	Setup menu	Same
Utilities	List of virtual keys	Same
System Setup	Password protected	Same
Vital signs Inputs		
ECG	3, 5 or 12 leads	Same
Frequency Response	Monitor Mode: 0.5 to 40 Hz Diagnostic: 0.05 to 150 Hz, Exercise : 1 to 25 Hz, -3 dB	Same
Input Impedance:	Typical 20 MΩ Minimum greater than: 5 MΩ differential, DC to 10 Hz; 2.5 MΩ differential 10 to 100 Hz 3 MΩ differential at 10 Hz	Same
Common Mode Rejection:	At least 100 dB at 50/60 Hz Without lead misbalance 86 db with lead misbalance The common mode rejection ratio is in accordance with ANSI/AAMI EC11 [9] Para. 3.2.11.	Same
Input Dynamic Range:	±5mV p-p at a rate up to 320mV/sec, as per ANSI/AAMI EC13 [8] Para. 3.2.9.1.	Same

	VitaLogik 6000/6500	Menntor X7
Input offset	± 300mV, as per ANSI/AAMI EC13 Para. 3.2.9.1.	Same
Gain:	Manual selection of 250, 500, 1000, 2000, 4000 and 8000 x ECG Signal impressed across selected lead	Same
Noise:	Less than 30 µ V p-p referenced to input	Same
Pacemaker Pulse Rejection:	Reject pulses from: 2.0 mV to 700 mV pulses of 0.2 to 2.0 mSec pulse widths and ≥ 3.0mV for 0.1mSec pulse width	Same
Defibrillator Protection:	Up to 5 KV. Amplifier Recovery time: < 3 seconds	Same
Lead Fault Sense:	On any ECG electrode	Same
QRS Detection:	0.25 to 5.0 mV, 70-120 msec width	Same
Synchronous Defibrillation Signal:	Pulse Width: 100 ms. Amplitude: 5 Vdc amplitude into 500Ω, short-circuit proof	Same
ECG Analog Output:	1 Volt / mVolt	Same
Heart Rate		
Range:	20 t0 350 bpm	Same
Accuracy:	Within 2 bpm	Same
Response Time:	Less than 7 sec for step change of 60 bpm from a base of 60 bpm	Same
Blood Pressure		Same
Input Sensitivity:	5 µvolts/volt/mmHg	Same
Transducer Excitation:	5 Volt	Same
Ranges:	-50 to +300 mmHg.	Same
Maximum variation during zero:	± 2 mmHg	Same

	VitaLogik 6000/6500	Menntor X7
Zero Accuracy:	± 0.2 mmHg	Same
Zero Drift:	Less than +/- 0.2 mmHg in 24 hours	Same
Transducer Load Impedance:	300 – 600Ω	Same
Linearity:	Better than 1% of full scale	Same
Common Mode Rejection:	80 dB minimum (reference to chassis 50/60Hz)	Same
Frequency Response:	DC to 12 Hz (DC to 40 Hz optional)	Same
Cardiac Output	Yes	Yes
Temperature		
Range:	27 °C to 45°C	Same
Accuracy:	± 0.2°C	Same
Respiration		
Frequency Response:	0.13 to 2.5 Hz., 3 dB bandwidth	Same
Range:	8 to 150 bpm	Same
Excitation:	65 kHz	Same
Pulse Oximetry (SpO2)		
Probe Type:	Masimo™ or Nellcor reusable or disposable	Same
Range:	0% to 100%.	Same
Pulse Rate Range:	20-250 bpm, below 20 displays zero	Same
Rate Accuracy:	± 3 bpm.	Same

	VitaLogik 6000/6500	Menntor X7
SpO2 Accuracy:	Determined by specific sensor: ±2 digits between 70% and 100% ±3 digits between 50% and 70%. ±3 digits between 70% and 95%.	Same
Non-Invasive Blood Pressure		
Method:	Oscillometric	Same
Initial Inflation:	150 mmHg (adult) 120 mmHg (pediatric).	Same
Pressure Accuracy:	Overall ± 3 mmHg, full scale.	Same
EEG		
Features	EEG + aEEG	Same
Number of channels	2	Same
Protection		
Defibrillator Pulse Protection	5KV as per ANSI/AAMI EC13 (9), clause 3.2.2.2 and per IEC 60601-2-27 (12), clauses 17,101 and 102	Same
Degree of protection against electrical shock	Type CF and BF. ECG, IBP and CO = CF NIBP and SpO2 = BF	Same
Electrosurgical Interference Suppression	Yes	Same
Displayed Waveforms		
ECG	Up to 12 lead	Same
BP	Up to 4, separate or superimposed	Same
Respiration	1	Same
SpO2	1	Same
EtCO2	1	Same

EEG	2 channels	Same
Displayed Numeric Parameters		
Heart Rate	Yes	Same
Respiration Rate	Yes	Same
SpO2	Yes	Same
BP – Systolic, Diastolic, Mean	Yes	Same
Temperature	2	Same
EtCO2	Yes (optional)	Plug in Module (option)
CerebraLogik interface	EEG & aEEG	Same
Alarm Indications	Yes	Same
Display Functions	**VitaLogik 6000/6500**	**Menntor X7**
Change ECG Lead Selection	YES	Same
Display of Arrhythmia Information	YES	Same
Data Review: Trends - Graphic	YES	Same
Data Review: Chart – Tabular	YES	Same
User defined Configuration Setup	YES	Same
User defined Default Settings	YES	Same
Accessories	Accessories	Same
GUI	Menu driven	same

Conclusion of comparison of technological characteristics:

We consider the Menntor X7 when used with the MPM inserted in the host Menntor X7 to be substantially equivalent to the VitaLogik 6000/6500 monitor and we submit that the differences between the two monitors do not raise any new issues of safety and effectiveness.

6. Spirometry Module

	Envoy Spirometry module	**Menntor X7** – Spirometry plug-in module

Spirometry module P/N	551-137-000	751-137-000
510K number	K030722 02/26/2004	
Module size:	Height: 10.0cm Width: 4.0 cm Depth: 14.0 cm	Height: 9.5cm Width: 4.0 cm Depth: 11.5 c
Display Function		
	Air Flow waveform	Same
	Volume waveform	Same
	Airway pressure waveform	Same
	Flow-volume loop	Same
	Pressure-volume loop	Same
	Pressure-flow loop	Same
	Derived parameters	Same
Pulmonary mechanics parameters	Vt_e. PIP, PEEP, MAP, Plat, PF_i, PF_e, RR, Ve, I:E, COMP, RES, RSBI	Same
Clinical Alarms for derived parameters	Visual & Sound Alarms	Same
Data Storage		
Trend of derived parameters	Yes – up to 3 months	Yes - up to 80 days
Chart of derived parameters	Yes– up to 3 months	Yes - up to 80 days
Waveforms of Flow, Volume and Pressure	Yes– up to 72 hours	Yes - 5 days
Specifications		
Degree of protection against electrical shock	Type BF applied part	Same
Sampling	100 sps	Same
Airway Adapter specification		
Flow Range:	2 - 180 lpm (33 - 3000 ml/s)	Same
Accuracy:	± 5 % reading, or 0.5 lpm	Same
Dead Space:	6.9 ml	Same

	Envoy Spirometry module	**Menntor X7** – Spirometry plug-in module
Connections:	Airway - 15 mm ID/22 mmOD patient end by 15 mm ID ventilator end (ISO 5356-1) Proprietary Smart connector. Tri-Tubing - triple 0.055" inch ID lumen	Same
Length:	2.5 inches (adapter) - 6 feet (tubing)	Same
Weight:	6.3 grams (minus tubing)	Same
Material:	Sensor - Polycarbonate (Makrolon). Tubing - Medical grade Polyvinyl Chloride	Same

Conclusion of comparison of Spirometry technological characteristics:

We consider the Menntor X7 Spirometry module to be substantially equivalent to the Envoy Spirometry module and we submit that the differences between the two monitors do not raise any new issues of safety and effectiveness.

The following table compares the major software element and/or changes done in the **Menntor X7** vs. the **VitaLogik 6000/6500,** predicate device (K131789 dated 27.12.2013) and also in (K093766 dated 7.2.2014)

SW Component	**VitaLogik 6000/6500**	Menntor X7
Display size	15 inch	Same
Display	All waveforms and numeric vital sings	Same
Operating System	QNX4	Same
GUI	Same	Same
Menus	Full set	Same
Vital signs 6000	Non invasive	Same
Vital signs 6500	Cardiac Output, 2 (4 optional) Invasive pressures	Same
LAN	Yes Optional Wireless LAN	Same
Optional Hardware enable	Touch screen	Same

We consider the Menntor X7 to be substantially equivalent to the VitaLogik 6000/6500 monitor and we submit that any differences between the two systems
• do not raise any new issues of safety and effectiveness

7. **Similarities and Differences in Design:**

Menntor X7 versus VitaLogik 6000/6500

The following technological and other characteristics/features apply to both the Menntor X7 and the VitaLogik.

- Intended for use in hospitals
- Do not change the functionality of the monitor
- Isolated inputs for vital signs sensors
- ECG amplifier front end with defibrillator protection
- Selectable filters for ECG
- Invasive BPs input circuit
- Non Invasive BP measurement
- SpO2 measurement
- Analog output for ECG and BP
- Display of vital signs and physiological waveforms
- Same GUI and same menus
- Monitors, Central Nurse Stations, Recorders and Printer on common LAN network
- Monitoring at central nurse station
- Optional Wireless LAN

The major differences between the Menntor X7 and the VitaLogik 6000/6500 are:

1. The Menntor X7 is a modular monitor, while the VitaLogik 6000/6500 is a configured monitor

2. EtCO2 on Menntor X7 is on a plug-in module as opposed to built-in on VitaLogik 6000/6500
3. Menntor X7 has a Spirometry module, that is not part of VitaLogik 6000/6500

8. Conclusion of comparison of technological characteristics:

We consider the VitaLogik 6000/6500 to be substantially equivalent to the VitaLogik 4000/4500 monitor and we submit that any differences between the two systems

- do not raise any new issues of safety and effectiveness

9. Verification, Validation and Testing

The Menntor X7 and it's MPM have been subject to extensive performance testing to ensure that:
1. The acquisition and display of the patient data and waveforms by the Menntor X7 remain the same for the predicate device VitaLogik 6000/6500.
Calibrated simulators were used to confirm the equivalence of each of the monitored Vital signs.
2. The acquisition and display of the Spirometry data and waveforms by the Menntor X7 remain the same for the predicate device Envoy Spirometry module.
3. The menu of the Menntor X7 is identical in response to the relevant menu items on the predicate device VitaLogik 6000/6500.
4. At the system level, SW Validation of the performance of the Menntor X7 as compared to the VitaLogik 6000/6500 system was carried out in accordance with the test plan described in the Mennen Medical Validation Test Procedure for the Menntor X7.
5. The SW Test Description for the Menntor X7 was derived from the SW Test Description for the VitaLogik 6000/6500 .
Final testing for the Menntor X7 included performance tests designed to ensure that the device meets all functional requirements and performance specifications, in accordance with the requirements of the Final Test Procedure for the Menntor X7.
6. Electrical Safety testing and EMC testing were performed by an independent testing laboratory to ensure that the device complies with applicable industry and safety standards.

10. Proposed Labeling

The system is called Menntor X7, and was assigned a P/N 791-000-000
The Multi Parameter Module is called MX57 and was assigned P/N 751-000-0XX

Page 1-1 of the Menntor X7 User Guide contains the following

Prescription Notice

CAUTION! *Federal law restricts this device to sale by or on the order of qualified medical personnel only.*

The following symbols appear on page 2-4 of the Menntor X7 User's Guide and on the front panel of the MPM. See the image of the front panel of the VitaLogik Menntor X7 on page 3-4 in the User manual.

"Attention – see Accompanying Instructions for Use"

Type BF Applied part (next to NIBP, SpO2, Temperature and EtCO2 connectors)

Type CF Applied Part – Defibrillation Proof

(next to ECG, IBP and CO connector)

Symbols and labeling on the front panel of the VitaLogik

11. Voluntary Standards

Appropriate voluntary standards for this device, to which conformance have been demonstrated:

- **IEC 60601-1:** (2005+A1:2012) Medical Electrical Equipment Part:1 General Requirements for Safety
- **IEC 60601-1-2** (2007+C11:2010): Medical Electrical Equipment Part 1-2: General Requirements for Safety - Collateral Standard: Electromagnetic Compatibility - Requirements and Tests.
- **IEC 60601-2-27** (2011):
  Medical electrical equipment, Part 2,
  Requirements for safety of electrocardiograph monitoring equipment.
- **IEC 80601-2-30** (2009+A1:2013): (was tested on the VL 6000-predicate device. the module wasn't changed)
  Medical electrical equipment, Part 2 - requirements for safety of automatic cycling indirect blood pressure monitoring equipment
- **IEC 60601-2-34** (2011): (was tested on the VL 6000-predicate device. the

module wasn't changed)
Medical electrical equipment, Part 2 - Particular requirements for the safety of direct blood pressure monitoring equipment

- **IEC 60601-2-49** (2011):
  Particular Requirements for the safety of multifunction patient monitoring equipment

- **IEC 60601-1-8** (2012):
  General requirements for safety-collateral requirements, test & guidance for alarm system in medical electrical equipment & medical electrical systems

12. Indications for Use

Device Name: **Menntor X7**
Menntor X7 is intended for use as a multi-parameter physiological patient monitoring system.
The Menntor X7, is a modular monitor with a Multi Parameter Module (MX57, MPM) that can monitor ECG/heart rate, invasive blood pressures , temperature, pulse oximetry, respiration, non-invasive blood pressure, and Cardiac Output
The Menntor X7 can also monitor EtCO2, Spirometry and EEG, and display aEEG.
The MPM (MX57) is equipped with a battery and can continue monitoring it's vital sign when out of the host Menntor X7
This effectively allows the Menntor X7 to monitor a wide-range of adult, pediatric and neonatal patient conditions, in many different areas of the hospital.
Functions include display of multi-parameter waveforms, vital signs, alarm & status messages.
The Mennen Medical Menntor X7 is intended for sale as a system for monitoring and recording patient information on any in-hospital application requiring patient monitoring.
The following are examples of intended clinical applications:

- Critical Care Patients
- Cardiac Step-down Units
- Emergency Departments
- Intra-operative (Anesthesia) Monitoring
- Post Anesthesia Care

*The Intended Use of the Menntor X7 monitor as indicated above is the same as the Indications for Use.